

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION**

IAN WALLACE,)	
)	
Plaintiff,)	
)	
v.)	Case No. 4:18-CV-1859 PLC
)	
PHARMA MEDICA RESEARCH, INC.,)	
et al.,)	
)	
Defendants.)	

MEMORANDUM AND ORDER

This matter is before the Court on Defendant Hikma Labs, Inc.’s (Hikma) motion for summary judgment. [ECF No. 94] Plaintiff Ian Wallace opposes the motion. [ECF No. 101] The parties submitted the same materials in support of their summary judgment positions.¹ For the following reasons, the Court grants Hikma’s motion.²

I. Background

This case arises from Plaintiff’s infection with hepatitis C, which he claims was caused by blood draws he underwent at Pharma Medica Research, Inc.’s (PMR) medical research facility in St. Charles, Missouri while participating in two medical studies. Roxane Laboratories, Inc. (RLI), a developer of pharmaceutical products that is now known as Hikma, sponsored one of the studies.³

¹ Specifically, both Plaintiff and Hikma submitted the: transcript of the November 7, 2019 deposition of Shabaz Kahn, M.D.; transcript of the July 30, 2019 deposition of Heather Jordan, M.D.; contract between Hikma and PMR, titled “Master Agreement”; and Hikma’s answers to interrogatories. Plaintiff also submitted Protocol 2016-4109, which pertains to the Hikma study in which Plaintiff participated that is at issue in this case.

² The parties consented to the jurisdiction of the undersigned pursuant to 28 U.S.C. § 636(c). [ECF No. 14]

³ In its statement of undisputed facts, Hikma stated that “[a]t the time of the clinical study [at issue], Hikma was known as Roxane Laboratories. On June 22, 2018, Roxane Laboratories, Inc. changed its name to Hikma Labs, Inc.” [ECF No. 96 at ¶ 8] The allegations in the second amended

The undisputed record reveals the following. In 2016, Plaintiff voluntarily participated in a study at PMR's St. Charles facility that was sponsored by Hikma. [ECF No. 96 at ¶ 7] During the study, participants were subject to multiple blood draws.

PMR is a contract research organization "engaged in the business of performing clinical studies and managing and monitoring clinical trials and analyzing clinical research data for pharmaceutical products." [ECF No. 96-2 at 1] Hikma retained PMR to conduct clinical studies of its pharmaceutical products, and they entered into a "Master Agreement." [ECF Nos. 96 at ¶ 6, 96-2]

The Master Agreement set forth the parties' contractual rights and obligations. [ECF No. 96-2] Among other things, the Master Agreement provided that PMR: could not make changes to study protocols without Hikma's approval; was responsible for negotiating investigator⁴ grants; agreed to "hold ... in strict confidence" all confidential information received from Hikma and "developed by the Investigators for [PMR]"; must permit Hikma to examine its records, standard operating procedures, and facilities; and was prohibited from subcontracting with any individual or entity that was "debarred under 21 U.S.C. 306(a) or (b)." [*Id.* at §§ 2.1, 4.6, 5.1-5.3, 16.1-16.4, 18.2] PMR also assigned Hikma "all right, title and interest to any and all Inventions, Discoveries and Improvements" developed by PMR's investigators. [*Id.* at § 11.1]

Under the section entitled "Independent Contractor," the Master Agreement stated:

[PMR] shall perform Services under this Agreement only as an independent contractor and nothing in this Agreement shall be construed to be inconsistent with that relationship or status. [PMR], its employees and consultants shall not

complaint and summary judgment materials refer to the sponsor of the study at issue as RLI. However, to minimize confusion, the Court will refer to this entity by its current name, Hikma.

⁴ The Master Agreement defined "investigator" to mean "any person conducting clinical trials in humans in connection with the Study, or any other person acting under the direction, control or authority of such person with respect to such clinical trials involving a Study Drug supplied by [Hikma]." [ECF No. 96-2 at § 1.2]

be considered employees or agents of [Hikma]. This Agreement shall not constitute, create or in any way be interpreted as, a joint venture, partnership or business organization of any kind between [PMR] and [Hikma]. No party shall have the authority to bind any other party to any agreement whatsoever.

[Id. at § 10]

Dr. Shabaz Khan was PMR's vice president of clinical operations. [ECF No. 96 at ¶ 10] Dr. Heather Jordan was a principal investigator at PMR's St. Charles facility from March 2015 to May 2019. [Id. at ¶ 25] Dr. Jordan's duties included ensuring each study assigned to her, including the ones in which Plaintiff participated, was conducted in accordance with the study's protocol.

PMR conducted each clinical study pursuant to a protocol, which "govern[ed] everything ranging from what medication to administer to the time a participant's blood [was] drawn and tested." [Id. at ¶¶ 24, 27] PMR's scientific affairs and protocol-writing teams drafted the protocols in accordance with Food and Drug Administration (FDA) guidelines and in consultation with the study sponsor. [ECF Nos. 96 at ¶¶ 17-21; 101 at 4 ¶ 4; 96-3 at 15, 17] In his deposition, Dr. Khan, explained that a study protocol must comply with FDA guidelines, but "any other studies [sic] specific design and all, the sponsor will have an input. It's their study." [ECF No. 96-3 at 16] Dr. Khan affirmed that the use of catheters rather than needles for blood draws would require the approval of both PMR's scientific affairs department and the study sponsor. [Id. at 22]

Plaintiff filed a second amended complaint asserting claims of negligence (Count III) and *res ipsa loquitur* (Count VI) against Hikma, RLI, and West-Ward Columbus, Inc. (WCI).⁵ [ECF No. 76] Plaintiff premised these claims on an agency theory. [Id.] Specifically, Plaintiff alleged

⁵ In the second amended complaint, Plaintiff alleged: "RLI has been succeeded by West-Ward Columbus, Inc. ... and/or by Hikma Labs, Inc." [ECF No. 76 at ¶ 4] In their answer, Defendants Hikma, RLI, and WCI denied this allegation. [ECF No. 82 at ¶ 4] The Court notes that WCI's name does not appear in any factual allegations outside the section of the second amended complaint entitled "Parties."

that: (1) Hikma “sponsored as master and PMR as agent a certain study at PMR’s St. Charles facility” in which Plaintiff participated; (2) Hikma contracted with PMR “to test on humans a certain medication designed, manufactured, supplied, and created” by Hikma; (3) Hikma “controlled the actions of [PMR] or had the right to control the actions of [PMR] in said study”; and (4) PMR was “acting as the agent for [Hikma] in the scope of its employment by [Hikma] for the aforesaid study.” [ECF No. 76 at 2, 5, 9] According to Plaintiff, Hikma is therefore “responsible for [PMR’s] actions during the study.” [Id.]

Hikma moves for summary judgment on the ground that PMR was not Hikma’s agent and, therefore, “any claims of negligence cannot be imputed to Hikma.” [ECF No. 94 at ¶ 4] In response, Plaintiff asserts that summary judgment is inappropriate procedurally and the evidence establishes the existence of an agency relationship between Hikma and PMR. [ECF No. 101]

I. Legal Standard

Summary judgment is proper if “the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a); Hill v. Walker, 737 F.3d 1209, 1216 (8th Cir. 2013). The movant “bears the initial responsibility of informing the district court of the basis for its motion” and must identify “those portions of [the record]...which it believes demonstrate the absence of a genuine issue of material fact.” Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). Once the moving party makes this showing, “the nonmovant must respond by submitting evidentiary materials that set out specific facts showing that there is a genuine issue for trial.” Torgerson v. City of Rochester, 643 F.3d 1031, 1042 (8th Cir. 2011) (en banc) (quotation omitted).

“On a motion for summary judgment, ‘facts must be viewed in the light most favorable to the nonmoving party only if there is a genuine dispute as to those facts.’” Ricci v. DeStefano, 557

U.S. 557, 586 (2009) (quoting Scott v. Harris, 550 U.S. 372, 380 (2007)). The court’s function is not to weigh the evidence but to determine whether there is a genuine issue for trial. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986); accord Tolan v. Cotton, 572 U.S. 650, 656 (2014) (per curiam) (quoting Anderson, 477 U.S. at 249). “Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge.” Torgerson, 643 F.3d at 1042 (quoting Reeves v. Sanderson Plumbing Prods., Inc., 530 U.S. 133, 150 (2000)).

In a diversity case, a federal court applies “federal law to matters of procedure, and state law to substantive matters. Gasperini v. Center for Humanities, Inc., 518 U.S. 415, 427 (1996).” Eagle Tech., Inc. v. Expander Ams., Inc., No. 4:11-CV-1763 HEA, 2014 WL 636172, at *3 (E.D. Mo. Feb. 14, 2014), aff’d, 783 F.3d 1131 (8th Cir. 2015); accord Smith v. Toyota Motor Corp., 964 F.3d 725, 728 (8th Cir. 2020). Therefore, this Court applies Missouri state law to the agency claims at issue in this motion for summary judgment.⁶

⁶ As the Court noted in its Memorandum and Order of August 2020, the parties do not dispute that Missouri law applies with respect to the substantive matters in this case. [ECF No. 108 at 7 n.8] “In a diversity action, a district court sitting in Missouri follows Missouri’s choice-of-law rules to determine applicable state law.” Stricker v. Union Planters Bank, N.A., 436 F.3d 875, 877 (8th Cir. 2006). When resolving “choice-of-law issues in tort actions, Missouri courts apply the ‘most significant relationship’ test.” Id. at 878 (citation omitted). The “most significant relationship” test

requires a court to consider: “(a) the place where the injury occurred, (b) the place where the conduct causing the injury occurred, (c) the domicile, residence, nationality, place of incorporation and place of business of the parties, and (d) the place where the relationship, if any, between the parties is centered.” [Goede v. Aerojet Gen. Corp., 143 S.W.3d 14, 24] n. 6 [(Mo. Ct. App. 2004)] (quoting Restatement (Second) of Conflict of Laws § 145 (1971))[, abrogated on other grounds by Sanders v. Ahmed, 364 S.W.3d 195, 206-08 (Mo. 2012) (en banc)].

Id.; accord Winter v. Novartis Pharms. Corp., 739 F.3d 405, 410 (8th Cir. 2014). “More importantly, for personal injury actions, Missouri applies the law of the place of injury, unless some other state has a more significant relationship. . . . Missouri’s formulation essentially

II. Discussion

Hikma claims that it is entitled to summary judgment because PMR, the party allegedly responsible for Plaintiff's injury, was not Hikma's agent. [ECF No. 95] More specifically, Hikma asserts that Plaintiff failed to plead, much less prove, the elements required to establish an agency relationship between Hikma and PMR.

Plaintiff counters that summary judgment is inappropriate because Hikma's "motion seems to be an attack on the sufficiency of the complaint allegations rather than ... a motion which posits that there is no genuine factual dispute." [ECF No. 101 at 6] Plaintiff further asserts that Hikma is not entitled to summary judgment because: (1) Hikma failed to present any affidavits or testimony in support of its motion; and (2) evidence in the summary judgment record supports the existence of an agency relationship between Hikma and PMR.

"Agency is the fiduciary relation that arises when one person (a principal) manifests assent to another person (an agent) that the agent shall act on the principal's behalf and subject to the principal's control, and the agent manifests assent or otherwise consents so to act." Blanks v. Fluor Corp., 450 S.W.3d 308, 378 (Mo. App. 2014) (quoting Restatement Third, Agency § 1.01). See also State ex rel. Ford Motor Co. v. Bacon, 63 S.W.3d 641, 642 (Mo. banc 2002). A principal is typically liable for the acts of its agent. Bacon, 63 S.W.3d at 642; McAllister v. St. Louis Rams, LLC, No. 4:16-CV-172 SNLJ, 2018 WL 1299710, at *3 (E.D. Mo. Mar. 13, 2018). To prove the existence of an agency relationship, a plaintiff must show that: (1) the agent had the authority "to alter legal relations between the principal and a third party"; (2) the agent was a "fiduciary with

establishes a presumption that the state with the most significant relationship is the state where the injury occurred." Winter, 739 F.3d at 410 (internal quotation marks and citations omitted). Here, the place of Plaintiff's injury is Missouri. Nothing of record supports a conclusion that a different state has a more significant relationship under the circumstances. Missouri substantive law therefore applies in this tort action.

respect to matters within the scope of the agency”; and (3) the principal had “the right to control the conduct of the agent with respect to matters entrusted to the agent.” Bacon, 63 S.W.3d at 642. The absence of any of these three elements defeats the purported agency relationship. Id.

“Whether an agency relationship exists is generally a factual question for the jury.” West v. Sharp Bonding Agency, Inc., 327 S.W.3d 7, 11 (Mo. App. 2010). “However, ‘this relationship is a question of law for the court to determine when the material facts are not in dispute, and only one reasonable conclusion can be drawn from the material facts.’” Id. (quoting Ritter v. BJC Barnes Jewish Christian Health Sys., 987 S.W.2d 377, 384 (Mo. App. 1999) (internal quotation omitted)). See also Weitz Co. v. MH Wash., 631 F.3d 510, 522 (8th Cir. 2011) (“[W]hen the facts are undisputed and only one reasonable conclusion can be drawn from them,” the existence of a principal-agent relationship “is a question of law.”).

In his second amended complaint, Plaintiff alleged that Hikma was liable for PMR’s negligence because Hikma “controlled the actions of [PMR] or had the right to control the actions of [PMR] in [the clinical] study” and was therefore PMR’s principal. [ECF No. 76 at 5, 9] In regard to Hikma’s alleged control over PMR, Plaintiff stated that Hikma had the right to:

visit [PMR’s] facility to assure compliance with [Hikma’s] instructions, policies, rules, protocols, and guidelines; monitor [PMR’s] conduct; request all information from [PMR] during the study; require reports from [PMR]; require audits; require quality assurance and quality control systems; require specific testing procedures including blood draws; regulate meal and sleep times of study participants; and all other restrictions set forth in the aforesaid study guidelines.

[Id.] Plaintiff also averred that Hikma required PMR to carry insurance for study participants.

[Id.]

As Hikma correctly points out in its motion for summary judgment, Plaintiff’s allegations relate solely to the third element of an agency relationship – namely, the principal’s right to control the agent. Plaintiff alleged no facts supporting the existence of either (1) PMR’s authority to alter

legal relationships between Hikma and third parties or (2) a fiduciary relationship between PMR and Hikma. The right to control the alleged agent is not sufficient to establish an agency relationship. See, e.g., Bacon, 63 S.W.3d at 642.

Plaintiff does not dispute Hikma's assertion that he failed to allege the first and second elements of an agency relationship between Hikma and PMR. Rather, without citing supporting Eighth Circuit or United States Supreme Court case law, Plaintiff argues that a defendant may not base a motion for summary judgment on pleading defects. Rule 56(c) provides:

A party asserting that a fact cannot be or is genuinely disputed must support the assertion by citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials....

Fed. R. Civ. P. 56(c)(1)(A). In this case, Hikma relies on the pleadings, as well as the Master Agreement and the depositions of PMR's employees, to establish that there is no genuine issue of material fact. When a plaintiff's pleadings and summary judgment materials fail to present facts demonstrating an essential element of his claim, summary judgment is appropriate. See, e.g., Clark v. SL Western Lounge, LLC, 4:18-CV-1223 JCH, 2019 WL 6893040, at *3–4 (E.D. Mo. Dec. 18, 2019).

Plaintiff also argues that Hikma's motion for summary judgment must fail because Hikma presented no proof, such as affidavits or testimony, to support its position that PMR was not its agent. [ECF No. 101 at 7] However, a nonmoving party must substantiate allegations with sufficient probative evidence that would allow a finding in his favor. Frevert v. Ford Motor Co., 614 F.3d 466, 473–74 (8th Cir.2010). “[A] movant will be entitled to summary judgment ‘against a party who fails to make a showing sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial.’” Bedford v. Doe,

880 F.3d 993, 996 (8th Cir. 2018) (quoting Celotex, 477 U.S. at 323). The existence of an agency relationship between Hikma and PMR is essential to Plaintiff's negligence and *res ipsa loquitur* claims against Hikma. As such, Hikma is entitled to summary judgment if the pleadings and summary judgment record do not make a showing sufficient to establish this relationship or to establish a dispute of material fact regarding the existence of such a relationship. Hikma's alleged failure to submit affidavits or testimony does not preclude summary judgment.⁷

Finally, Plaintiff opposes Hikma's motion on the ground that evidence in the summary judgment record establishes the three elements of an agency relationship between Hikma and PMR. In regard to the first element, Plaintiff maintains that the Master Agreement authorized PMR to alter Hikma's legal relationships because it: prohibited PMR from changing study protocols without Hikma's approval; gave Hikma the right to access PMR's facility to observe testing and review records; and prohibited PMR from contracting with debarred companies. [ECF No. 101 at 8-9] Additionally, Plaintiff points out that the Master Agreement required PMR to: negotiate investigator grants; obtain Hikma's approval before retaining a subcontractor; include in

⁷ According to Plaintiff, Hikma's motion for summary judgment "seems to be illustrative of forbidden summary judgment motions which a defendant files simply to force a plaintiff to map out all their evidence before trial or risk dismissal." [ECF No. 101 at 5] In support of his position, Plaintiff cites Goka v. Bobbit, 862 F.2d 646 (7th Cir. 1988). To the extent that this Court should consider Seventh Circuit case law, Goka is distinguishable and unpersuasive under the circumstances. There, the defendant prison guards moved for summary judgment on the *pro se* inmate's section 1983 claims, claiming that there were no material factual disputes, even though they were aware of evidence to the contrary. Id. at 650. Reversing the district court's entry of summary judgment for the defendants, the Seventh Circuit reasoned that a party "defeats th[e] purpose" of Rule 56 when it "has obtained knowledge through the course of discovery ... that a material factual dispute exists and yet proceeds to file a summary judgment motion, in hopes that the opposing party will fail or be unable to meet its burden in responding to the motion[.]" Id. Unlike the parties in Goka, Plaintiff is represented by counsel and Hikma does not ignore evidence that is "directly and materially inconsistent" with the material facts upon which it relies.

any investigator contracts the Master Agreement’s provisions concerning the assignment of intellectual property rights to Hikma; and designate a specific person to serve as PMR’s “agent” for handling the Hikma account. [Id.]

Based on its review, the Court finds that the Master Agreement evidences Hikma’s intention to retain control over the testing of its pharmaceutical products by, among other things, overseeing PMR’s work and limiting PMR’s ability to subcontract out its duties and obligations under the agreement. The Master Agreement also reflects Hikma’s intent to protect its confidential information and enjoy the benefits of any intellectual property flowing from the work PMR performed under the agreement. However, nothing in either the Master Agreement or the other evidence of record suggests PMR had the authority to alter Hikma’s legal relationships with third parties. See, e.g., McKeage v. Bass Pro Outdoor World, LLC, No. 12-3157-CV-S-GAF, 2015 WL 2093126, at *7 (W.D. Mo. May 5, 2015) (“While Plaintiffs have put forth some evidence regarding the alleged principals’ abilities to control the alleged agent, no evidence or arguments have been made that [the alleged agent] in any way had the power to alter the legal relationships between [the alleged principals] and their customers.”); Hagale Indus., Inc. v. Lands’ End, Inc., No. 3474-CV-S-4-ECF, 2002 WL 35646232, at *7 (W.D. Mo. Oct. 29, 2002) (evidence that the defendant limited the plaintiff’s ability to subcontract or use new facilities without the defendant’s approval “does not even raise a question as to whether [the defendant] had the power to bind [the plaintiff] in legal matters, or vice versa.”). Indeed, the Master Agreement expressly stated that “[n]o party shall have the authority to bind any other party to any agreement whatsoever.”⁸ [ECF No. 96-2 at § 10]

⁸ In a conclusory statement without citation to the summary judgment record, Plaintiff states: “[PMR] had the contractual right to alter relationships on [Hikma’s] behalf ... concerning contracts with study participants, contractors, insurers, the U.S. Patent and Trade Mark Office, and legal counsel.” [ECF No. 101 at 11] Contrary to Plaintiff’s statement, however, the relevant contractual provisions related to PMR’s right to contract on its own behalf, not on Hikma’s behalf. “Where a

Because Plaintiff neither pleaded facts nor presented evidence demonstrating that PMR had the authority to alter legal relationships between Hikma and third parties, Plaintiff failed to establish the existence of an agency relationship between Hikma and PMR.⁹ See McKeage, 2015 WL 2093126, at *7. Hikma is entitled to judgment as a matter of law and the Court therefore grants Hikma's motion for summary judgment.

III. Conclusion

For the foregoing reasons,

IT IS HEREBY ORDERED that Hikma's motion for summary judgment [ECF No. 94] is **GRANTED**.

IT IS FURTHER ORDERED that Plaintiff's Counts III and VI against Defendants Hikma, RLI, and WIC are **DISMISSED with prejudice**.



PATRICIA L. COHEN
UNITED STATES MAGISTRATE JUDGE

Dated this 11th day of February, 2021

contract only alters the legal relationship of the alleged agent and a third party, not the legal relationship of the alleged principal and a third party, the first element of an agency relationship is not satisfied.” Ackerman v. Global Vehicles U.S.A., Inc., No. 4:11-CV-687 RWS, 2012 WL 694834, at *4 (E.D. Mo. Mar. 1, 2012).

⁹ Where a plaintiff fails to either allege facts or present evidence demonstrating the first element of agency relationship under Missouri law, a court need not consider the other elements. See Affordable Communities of Missouri v. Federal Nat. Mortg. Ass'n, 714 F.3d 1069, 1074 (8th Cir. 2013).